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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,133	10/20/2005	Clifford J Herman	1332 WO/US	9352

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
06/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,133	HERMAN, CLIFFORD J	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *24-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I, namely claims 1-23, in the reply filed on 4/30/2007 is acknowledged. It is requested that Applicant submit a clear copy of claims 1-23 in response to this Office Action and use identifiers such as 'currently amended', 'withdrawn', or 'new/cancelled' etc. to denote all the claims. Examiner, for the sake of compact prosecution, is examining the claims instead of sending a ~~Notice~~ Notice of Improper Amendment.

Objections

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: there is no reference of priority to PCT/US04/33268.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 recites the limitation "ascorbic acid". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Midha et al. (US Patent 6,127,385) in view of Epstein et al. (US Pg-Pub 2002/0103162).

Midha et al. teach solutions comprised of methylphenidate that is dissolved in an aqueous or non-aqueous solvent such as propylene glycol and an organic acid such as ascorbic acid (meeting the limitations of claims 9-10, 12, 14-15, 17 and 19; Col. 4, lines 59-63). The solution further contains aromatic oils as flavoring agents (meeting the limitations of claims 13, 18 and 23; Col. 4, lines 59-63). Midha et al. further teach that injectable solutions may be prepared using water (further meeting the limitation of claims 9, 14 and 19; Col. 5, lines 21-23).

Midha et al. do not teach the antioxidant as any listed in claim 1, the amounts of each component listed, the specific polyols listed in claims 11, 16 and 21 or the glycol listed in claim 22.

Epstein et al. teach pharmaceutical preparations comprised of methylphenidate compounds. It is taught that the preparations may be formulated in a biologically acceptable medium, such as water (solvent) and polyols (non-aqueous solvent; with glycerin, sorbitol and polyethylene glycol listed) and mixtures thereof (meeting the

limitations of polyols in claims 11, 16 and 21; paragraph 0250 and 0268). It is further taught that antioxidants may be present in the composition, with citric acid being amongst the possible antioxidants listed (meeting the limitations of claims 1, 3 and 7; paragraph 0274). Epstein et al. also teach the use of flavoring agents (paragraph 0273; meeting the limitation of claim 8).

Furthermore, it is obvious to vary and/or optimize the amounts of methylphenidate, organic acid and aqueous and non-aqueous solvents provided in the composition, according to the guidance provided by Midha et al. and Epstein et al. to provide a composition having the desired properties such as the desired concentrations and percentages of each component to formulate an effective methylphenidate solution for administration. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention to combine the teachings of Midha et al., which teach pharmaceutical solutions comprised of methylphenidate and an organic acid dissolved in propylene glycol and water, with the teachings of Epstein et al. which teach methylphenidate preparations as well and include citric acid as an organic acid that can be used in the composition, as well as a solvent and non-aqueous solvents. One would be motivated to use the citric acid taught by Epstein et al. in the composition of Midha et al. because Midha et al. teach solutions comprised of organic acids and there would be a

reasonable expectation of success that citric acid would be effective in the composition as taught by Epstein et al.

Conclusion

No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER